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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,047	02/19/2004	Michael Pesachovich	1662/62102	5742
26646	7590	08/09/2005	EXAMINER	
KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004			GEHMAN, BRYON P	
			ART UNIT	PAPER NUMBER
			3728	
DATE MAILED: 08/09/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/782,047

Applicant(s)

PESACHOVICH ET AL.

Examiner

Bryon P. Gehman

Art Unit

3728

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/7/04</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

Art Unit: 3728

1. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

2. The abstract of the disclosure is objected to because it relates to nothing not generally well known in the art. Correction is required. See MPEP § 608.01(b).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

Art Unit: 3728

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 16, the phrase "HPLC relative to retention times of about 0.26, 0.34, 0.37, or 0.80" is indefinite, as the specification fails to disclose the meaning of the acronym "HPLC" or the meaning of the decimal values provided therefor.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 4, 12, 16 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 4, "additional layer of aluminum" lacks antecedent basis from claim 1.

In claim 12, lines 1-2, "the gas impermeable" is indefinite, as the terms have antecedent basis merely as adjectives.

In claim 16, the phrase "HPLC relative to retention times of about 0.26, 0.34, 0.37, or 0.80" is indefinite, as it is not clear what "HPLC" is or the conventionality of the retention times expressed as decimals.

In claim 19, line 2, "later" should be --layer--.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 3728

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

7. Claims 1-14 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Tenengauzer et al. (6,764,997). Disclosed is a container for packaging azithromycin made of gas impermeable material wherein after storage azithromycin degradation products are limited (see column 16, line 34 through column 17, line 21).

As to claims 3-4 and 9, a laminated aluminum bag is disclosed (column 16, lines 42-47).

As to claim 5, the azithromycin is disclosed in a solvate form.

As to claims 7 and 8, azithromycin monohydrate is disclosed

As to claim 10, a bag is disclosed.

As to claim 13, the disclosed test occurred at 55 degrees C.

As to claim 14, 60% relative humidity is ordinary atmosphere as disclosed.

8. Claims 17-19 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Tenengauzer et al.. See the immediate paragraph. The methodology is simply the use of the described structure.

Art Unit: 3728

9. Claims 1-4 and 10-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Schuler et al. (2005/0051453). Disclosed is a sealed container for packaging azithromycin made of gas impermeable material wherein after storage azithromycin degradation products are inherently limited (see page 3, section 37 and page 7, section 54) by use of a laminated aluminum bag.

As to claim 5, the azithromycin is disclosed in a solvate form.

As to claims 7 and 8, azithromycin monohydrate is disclosed

As to claim 10, a bag is disclosed.

As to claim 13, the disclosed test occurred at 55 degrees C.

As to claim 14, 60% relative humidity is ordinary atmosphere as disclosed.

10. Claims 17-19 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Schuler et al.. See the immediately preceding paragraph. The methodology is simply the use of the described structure.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 5-9 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over either one of Tenengauzer et al. and Schuler et al.. To any degree the forms of

azithromycin and previously held inherent parameters can be argued as not expressly disclosed, these features are held to be obviously attainable given the disclosure of either one of Tenengauzer et al. and Schuler et al..

13. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lechzik et al. (3,331,495) in view of any one of Curatolo et al. (5,605,889), Tenengauzer et al. and Schuler et al.. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dobler et al. (2004/0104142) in view of any one of Curatolo et al. (5,605,889), Tenengauzer et al. and Schuler et al.. Lechzik et al. and Dobler et al. each disclose a container for packaging degradable medicine made of gas impermeable material wherein after storage degradation products of the medicine are inherently limited by use of a sealed laminated aluminum bag. Curatolo et al., Tenengauzer et al. and Schuler et al. each disclose providing azithromycin in a protective container. To modify the container of either one of Lechzik et al. and Dobler et al. to employ the container specifically for azithromycin would have been obvious in view of any one of Curatolo et al., Tenengauzer et al. and Schuler et al. in order to protect the azithromycin from degradation, as disclosed by either one of Lechzik et al. and Dobler et al..

As to claims 3-4 and 9, a laminated aluminum structure is disclosed by either one of Lechzik et al. and Dobler et al..

As to claims 5-8, the azithromycin is disclosed or suggested in various forms by one of Curatolo et al., Tenengauzer et al. and Schuler et al..

As to claims 13-16, to the degree the previously held inherent parameters can be argued as not expressly disclosed, these features are held to be obviously attainable given the disclosures of the prior art taken as a whole.

14. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lechzik et al. in view of any one of Curatolo et al., Tenengauzer et al. and Schuler et al.. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dobler et al. in view of any one of Curatolo et al., Tenengauzer et al. and Schuler et al.. See the immediately preceding paragraph. The methodology is simply the use of the described structure.

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Disclosed are containers of azithromycin.

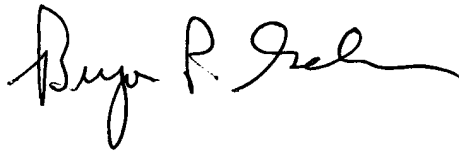
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bryon P. Gehman whose telephone number is (571) 272-4555. The examiner can normally be reached on Monday through Wednesday from 5:30am to 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu, can be reached on (571) 272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 3728

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Bryon P. Gehman". The signature is fluid and cursive, with a long horizontal stroke at the end.

Bryon P. Gehman  
Primary Examiner  
Art Unit 3728

BPG